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09/864,488	05/24/2001	Marcia A. Wise	7733.D2	3552
7590 12/02/2008 FAY KAPLUN AND MARCIN, LLP 150 BROADWAY, SUITE 702 NEW YORK, NY 10038			EXAMINER GRAY, PHILLIP A	
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/864,488  
Filing Date: May 24, 2001  
Appellant(s): WISE ET AL.

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Wise et al.  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 4/23/2008 appealing from the Office action mailed 10/09/2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

### **WITHDRAWN REJECTIONS**

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner.

(withdrawn rejection) Claim 56 is unpatentable under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

(withdrawn rejection) Claims 56, 59-66, 68-69, and 80 is unpatentable under 35 U.S.C. 102(b), as being anticipated by Claderon.

### **(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

### **(8) Evidence Relied Upon**

4,771,777	Horzewski et al.	9-1988
4,867,742	Calderon, Reynaldo	9-1989
5,128,540	Wijay et al.	10-1992
5,176,698	Burns et al.	1-1993
5,403,274	Cannon, Louis	4-1995

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 56, 59-66, 68-69 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Wijay (U.S. Patent 5,158,540).

Wijay discloses a low profile angioplasty perfusion catheter and method of use, which is insertable through a guiding catheter (see abstract, figures 1-4). Wijay discloses and teaches (and is fully capable of being) a system for establishing intermittent fluid communication within a patient's bloodstream, and comprises a catheter with first (such as annular passage 30) and second lumens (26) (see figures 2, 3, and paragraph at column 2 line 49-68), a first sealing balloon (16) positionable within the first lumen to prevent blood (or fluid) flow therein (or through) and a deflation mechanism for deflating the balloon (not numbered but described and to be connected to connection 3)(see detailed description at column 3 lines 49-61). Further Wijay discloses a method of sealing the catheter that comprises the acts of advancing the first deflated balloon (22) along the first lumen (30) and inflating the balloon to seal the lumen at the distal end thereof which would prevent fluid flow from entering or exiting (see description of use at column 4 lines 10-46) the distal end of the lumen. Wijay discloses that the balloon could be **selectively** inflated or deflated (see column 3 line 54-55) to seal passage 30 which is in fluid communication between blood vessel site and proximal end of catheter (nearer section 2 as in figure 1). Therefore it is examiners position since the proximal balloon can be selectively inflated and deflated (and since it blocks the flow through passage 30 while inflated) when the balloon is deflated ingress or egress of fluid flow through passage 30 would occur. And it is examiners position that this deflation (as previously noted) would take place while the catheter is in the

blood vessel site. Further Wijay discloses a stem (near 14) within the lumen, and further the stem is fully capable of being selectively displaceable along the lumen through the central opening of the in the seal (as shown in figure 1 and describe in columns 2-4 generally). There are further ports adjacent the proximal end by which a flushing liquid under pressure is displaced within the lumen (i.e. 2,3,4,28, or 7). Further Wijay discloses steps of advancing a first balloon along a catheter and inflating the balloon to seal the catheter, deflating the ballon to open the seal and causing ingress or egress, further the balloon (and Wijay PTCA catheter) is withdrawn from the guiding catheter after the balloon is deflated (see column 2-4), and this method may be done multiple times for multiple treatments (since it is selectable) and it is examiners position that the lumen is purged with saline (column 4). Wijay discloses a device that contains a catheter (8, or 13) a balloon with stem (16) and a deflating mechanism and port (discussed above) and these elements are fully capable of satisfying all structural, operational, functional, and spatial limitations of the claims as currently written.

Claims 56, 59-66, 68-69 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Horzewski (U.S. Patent 4,771,777). As discussed above and see figures 9 and see catheter 14 balloon 82 and stem 77 port 26 for example.

Claims 56, 59-66, 68-69 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Calderon (U.S. Patent 4,867,742). As discussed above and see figures 2,3, and 5 and catheter 52, ballon 56 , and ports 58,54,26, or 14.

Claims 56, 59-66, 68-69 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Cannon (U.S. Patent 5,403,274). As discussed above and see figures 1-3 and catheter 18 balloon 44 with stem near 32 and ports shown in figure 1 at proximal end of catheter.

Claims 59-64 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wijay (U.S. Patent 5,158,540) in view of Burns (U.S. Patent 5,176,698). Wijay discloses the method substantially as claimed except for explicitly stating purging the first lumen. Burns discloses purging the first lumen (abstract and entire specification). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to purge the catheter of Wijay as taught by Burns to vent unwanted gases and liquids. As to claims 60-62 (Burns col. 2) as to claim 63, (figure 6); as to claim 64, (the terminating act is performed by purging see above)

Claims 70-72, 74-79 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijay (U.S. Patent 5,158,540), or alternatively Horzewski et al. (U.S. Patent 4,771,777), or alternatively Claderon (U.S. Patent 4,867,742), or alternatively Cannon (U.S. Patent 5,403,274). Wijay and alternatively Horzewski/Claderon/ or Cannon discloses the claimed invention and method except for being a side by side nonconcentric catheter tube/balloon. (applicant is merely attempting to claim two of the

identical aforementioned tubes not having a common center) It would have been obvious to one having ordinary skill in the art at the time the invention was made to duplicate the device of Wijay or Horzewski/Calderon/ or Cannon, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8 (CA7 1977), and this would provide twice the output or input capabilities as well.

#### **(10) Response to Argument**

**Applicant' first argument** is moot since the rejection under U.S.C. 112 has been withdrawn.

**Applicant' second argument** is that the claim language "*so that, when inflated, the first balloon seals the distal end of the first lumen to prevent flow therein*" is a structural limitation which clearly defines physical characteristics of the balloon and its relation to the rest of the claimed combination.

It is examiner's position that Wijay does disclose both the structures and the functions carried out by those structures as defined in the claims. Examiner is of the position that as shown in Figure 1 of Wijay, the balloon (16) when inflated seals the distal end (downstream end distal of 3 line) of the first lumen (annular passage 30) to prevent flow therein (as described in column 3 lines 41-52 and column 4 lines 16-18 and how Wijay seals to prevent flow). Examiner is of the position the Wijay balloon would have all the structure and related functions of the claimed Limitations.



**Applicant's third argument** is that Horzewski does not teach "*a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end therethrough*" and "*the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*".

It is examiner's position that Horzewski contains a first lumen (interior of 12, as passage near 18) and a second lumen (port lumen through 26 or multi lumens through element 77 shown in figures 6 and 7) and they extend from a proximal end (near 23 side) to distal end (near 17 side) and that the first balloon (82/86) does seal the distal end to prevent blood flow thereinto (see Horzewski paragraphs at column 7 lines 19-21 which describes the balloon sealing the first lumen).

**Applicant' fourth argument** is moot since the rejection under has been withdrawn.

**Applicant's fifth argument** is that Cannon does not teach "a catheter including first and second lumens extending therethrough from a proximal end of the catheter of a distal end thereof" and "when inflated the first balloon seals the distal end of the first lumen to prevent blood flow thereinto".

It is examiner's position that the first balloon of Cannon (44) seals the distal end of the first lumen (near 46 interior of 12), and note second lumen interior (lumen 32) as shown in figure 3 and 2). Examiner draws attention to Cannon column 5 lines 55-60 which states that "the inflation of the trapper balloon 44 effectively seals the distal end of the guide catheter 12".

**Applicant's sixth argument** is that Wijay and Burns do not suggest "a first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen".

Again as stated above, it is examiner's position that Wijay does disclose both the structures and the functions carried out by those structures as defined in the claims. Examiner is of the position that as shown in Figure 1 of Wijay, the balloon (16) when inflated seals the distal end (downstream end distal of 3 line) of the first lumen (annular passage 30) to prevent flow therein (as described in column 3 lines 41-52 and column 4 lines 16-18 and how Wijay seals to prevent flow) Examiner is of the position the Wijay balloon would have all the structure and related functions of the claimed limitations.

**Applicant's seventh argument** is a reiteration of the previous arguments to each of the prior art (Wijay, Horzewski, and Cannon) references individually as discussed above as the disclose in the 35 U.S.C. 103(a) rejection.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

For the same reasons as stated above, it is Examiner's position that Wijay, Horzewski and Cannon all teach catheters which have first and second lumens (identified above and in the final rejection) "*that extend therethrough between proximal and distal ends*" and first and second balloons. As discussed in the final rejection the

prior art discloses the claimed invention and method except for being a side by side nonconcentric (coaxial) catheter /tube/balloon. (applicant was attempting to claim two of the identical aforementioned tubes not having a common center). A duplication of the Wijay, Horzewski, or Cannon prior art would satisfy this limitation. It is examiner's position that a duplication of the essential working parts of a device involves only routine skill and would be an obvious modification to produce a greater output or input of the device (i.e. having two of the device instead of one).

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Phillip Gray

/Phillip Gray/

Examiner, Art Unit 3767

Conferees:

/Kevin C. Simmons/

Supervisory Patent Examiner, Art Unit 3767

/Janet C. Baxter/  
TC 3700 TQAS